

Applicant : Qiwang Xu et al.  
For : THE USE OF N-ACETYL-D-GLUCOSAMINE FOR PREPARING  
MEDICINES FOR UROGENITAL TRACT INFECTION'S  
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In the Specification:

Please amend paragraph [0002] with the following amended paragraph.

Urogenital tract infection is a common disease, which is chronic and refractory and greatly interferes with a patient's normal life. At present, the main medicaments for treating urogenital tract infection mainly are broad spectrum antibiotics and Chinese lotion. However, the abuse of broad spectrum antibiotics results in drug resistance in microorganisms causing urogenital tract infection, so that the ~~therapeutical~~ therapeutic effect became worse and worse although the dose of antibiotics ~~increases~~ increased gradually. On the other hand, the conventional treatment with antibiotics can hardly bring about better effect. For example, condyloma acuminatum virus can hardly be treated. In addition, the treatment of urogenital tract infection with Chinese lotion also has disadvantages, for ~~main examples~~ example, unremarkable effect, inconvenient use, and contamination of clothing. Hence, a medicament for effectively treating urogenital tract infection is in need ~~all the time~~.

Please amend paragraph [0003] with the following amended paragraph:

In the research of "bio-waves" theory, the present inventor has set up a bacterial wave growth model. Through researching, it is known that this wave is of its intrinsic regulation mechanism: some chemical substances are able to participate the regulation in the bio-wave process, so as to transform an abnormal periodic slow wave into a normal physiological chaotic quick wave, and ~~this~~ these kind of substances are known as promoting wave factors. Through separating, purifying and identifying, it is determined that one of the factors is N-acetyl-D-glucosamine, the promoting wave function of which is shown in regulating the coupling oscillation of cellular membrane protein and sugar coating. Many biochemical and physiological ~~process~~ processes of the human body need the participation of the promoting wave factors, and it would lead to an abnormal state, if ~~this~~ these kind of promoting wave factors ~~is lacked~~ are lacking in the living body.

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Please replace paragraph [0004] with the following amended paragraph:

N-acetyl-D-glucosamine is a chemical reagent. From the 1990s, it ~~is~~ has been continually used to treat diseases such as pericementitis (WO9102530A1), intestinal inflammation (WO9953929A1), cornea disease (JP10287570A2), hypertrophy of the prostate (US05116615), organic pathologic changes of lower digestive tract mucous membrane (WO93/1475), etc. as a tissue growth regulation agent (WO/8702244), and in cosmetology (JP59013708A2), shampoo preparation (JP2011505A2), etc., but ~~is it~~ it has not been used in the manufacture of a medicament for treating urogenital tract infection.

Please replace paragraph [0005] with the following amended paragraph:

The present invention surprisingly discovers that N-acetyl-D-glucosamine can be used to ~~effective~~ effectively treat urogenital tract infection. This discovery is surprising because the heal of urogenital tract infection needs to control microorganism infection, to treat topical exudation, to eliminate tissue inflammatory edema and pains, to promote tissue repair, and so on, and a doctor usually provides a combination of several medicaments, while N-acetyl-D-glucosamine could be used as the only active ingredient in a medicament for healing urogenital tract infection.

Please replace paragraph [0009] with the following amended paragraph:

N-acetyl-D-glucosamine is commercially available from the market or prepared according to a known method. For instance, WO97/31121 discloses a method for preparing N-acetyl-D-glucosamine from chitin by an enzyme method. JP63273493 ~~has~~ discloses a method comprising partially hydrolyzing chitin to obtain N-acetyl-chitose, and then treating it with an enzyme to obtain N-acetyl-D-glucosamine.

Please replace paragraph [0011] with the following amended paragraph:

The compound of the formula (I) or its pharmaceutically acceptable salt is used as a main active component in combination with several pharmaceutically acceptable excipients

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and/or carriers to prepare a topical formulation form such as aqua, emulsion, cream, lotion, ointment, suppository, etc. for treatment of urogenital tract infection. The amount of the active component is 0.1 to 10%, preferably 0.2 to 6% relative to the whole formulation. The daily dose of said medicament is 10 to 10000 mg, preferably 50 to 5000 mg, more preferably 100 to 2000 mg of N-acetyl-D-glucosamine per person.

Please replace paragraph [0012] with the following amended paragraph:

The composition of the present invention in the form of topical formulation, such as solution, emulsion, suspension, viscoloid, cream, ointment, etc. for topically daubing or washing, can be prepared by mixing the active component with one or more pharmaceutically acceptable carriers and additives, such as water, polyethylene glycol, glycerin, Vaseline, xanthan gum, alcohols, etc. as a dissolving agent, lubricant, binder, preservative, stabilizer, and in combination with an ecological regulator such as lactic acid according to general techniques as well known by the person skilled in the art. In addition, a propellant can be added to said formulation to prepare an aerosol for topically spraying. For example, an aerosol has a formulation comprising 1% N-acetyl-D-glucosamine, 3% lactic acid and 0.3% sodium benzoate.

Please replace paragraph [0013] with the following amended paragraph:

Unrestricted to any theory, the inventor deems the effect of the compound of formula (I) of the present invention for treatment of urogenital tract infection is achieved by adjusting the redistribution of body cells. "Cell redistribution" means the ~~continue~~ continued position alternation of body tissue cells of microorganism cells and the rhythmic alternation of coagulation-dissolution state of biological macromolecules in cells. N-acetyl-D-glucosamine brings about a special function by regulating cell redistribution in different levels. The alternation of macroscopic cell position represents the feature of the cell growth in a wave manner. N-acetyl-D-glucosamine regulates the growth of body cells and microorganism cells in a normal wave manner, so that microorganisms cannot be topically transplanted. As for

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microecological function, the normal bacteria growth is supported, and the supplement of ecological bacteria is not employed, so that the disadvantage of adaptability of the supplementary bacteria is avoided. In terms of promoting repair of skin and mucous membrane tissues, the product of the present invention exhibits unique effects for controlling inflammation, damage, infection, and exudation. Thus, the product of the present invention can be widely used for controlling conditions and for essential treatment.

Please replace paragraph [0022] with the following amended paragraph:

The *Proteus Mirabilis* were inoculated at the center of an LB plate, incubating at 37°C for 9 hours, then ~~there were~~ concentric rings emerged, which were extended outward continually with an interval of 3 hours, and this was taken as a control; adding the compound of formula (I) with a final concentration of 0.5% onto the LB plate, the *Proteus Mirabilis* were inoculated by the same method, cultured at 37°C, and the result showed that not only the concentric rings formed with an interval of 3 hours were emerged, comparing with the control, it can be seen that there were also many fine waves on each ring ~~emeraged~~ emerged.

Please replace paragraph [0025] with the following amended paragraph:

The experiment adopts a bio-wave model which is used to research the promoting wave function of the compound of formula (I). It can be seen from the result that the compound of formula (I) was not only able to cause a bacterial cell to reveal a normal bio-wave characteristic, but also ~~cause~~ caused the wave to reveal finer wave mode, and these indicated that the compound of formula (I) have a promoting function to bio-waves, and the promoting wave function is able to participate in the repair and redistribution of skin cells.

Please replace paragraph [0035] with the following amended paragraph:

The results from these tests showed that in the acute toxicity test of the compound of formula (I), the dosage of ~~more than~~ than 2 g/kg was taken, which was 300 times ~~than~~ the injection dosage for human ~~being~~ beings, but the acute toxicosis reaction had not appeared yet;

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in the long-period toxicity test, the maximum dosage had reached up to 1 g/kg, and after the treatment and observation for four weeks, there was no intoxication reaction yet; and in the reproduction test, the mouse was ~~feed~~ fed from a routine dosage of 7 mg/kg for 3 generations, it had been proved that the compound of formula (I) had no influence on the pregnancy, birth, nurse and the growth of the baby mouse, so that the compound of formula (I) is a substance without toxicity.

Please replace paragraph [0043] with the following amended paragraph:

The present invention pioneers a novel medial use of N-acetyl-D-glucosamine, extends the application range of N-acetyl-D-glucosamine, and increases the use value of N-acetyl-D-glucosamine. The external formulations in various forms prepared with N-acetyl-D-glucosamine as ~~active-component~~ components are used as a medicament for prevention and treatment of urogenital tract infections, and exhibit advantages of easy preparation and no toxic and side effect. Since it is a colorless, insipid and nonirritant substance, and has a novel action route, its use exhibits unique ~~therapeutical~~ therapeutic effect and avoids disadvantages of other products.